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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,061	10/06/2000	James M. Robl	P 0275492 23523-0168	7154
909	7590	02/23/2004	EXAMINER	
PILLSBURY WINTHROP, LLP			TON, THAIAN N	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	

1632

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/685,061

Applicant(s)

ROBL ET AL.

Examiner

Thai-An N Ton

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 06 January 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 51-66,69-102 and 105-146.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper ~~Not~~ filed 1/5/04

10. ☐ Other: _____

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630

Continuation of 2. NOTE: The amendments to the claims raise new issues that require further consideration with regard to 112, 1st and 112, 2nd. For example, the recitation of "the animal" raises new issues of 112, 2nd paragraph.

Applicants' arguments have been considered but are not found to be persuasive. Applicants' argue that claim 51, as amended now specifically indicates what ungulate animals the claims pertain to. See p. 18 of Applicants' response. Applicants' Amendments have not been entered, thus the rejection of record is maintained. The breadth of the claims is directed to any ungulate species. It is reiterated that heteroplasmy may occur between sub-species, but this phenomenon does not necessarily extend to every species, or to all cell types. Further, although cybrids may develop, unpredictable factors such as maternal incompatibility and the inability of the cybrid to develop renders the NT art, in a general sense, unpredictable. Applicants cite Chen as support to show the predictability of cross-species NT. Chen teaches the generation of cybrids but fails to show fully formed animals, as required by some of the instant claims, which would demonstrate the totipotency of the NT-generated cells. Applicants further point to Loi for support that cross-species NT is predictable, wherein granulosa cells from two female moulons were transferred into enucleated sheep oocytes. This is a teaching with regard to sub-species NT - the mouflon is *O. orientalis musimon* and a domestic sheep is *O. aries*. As stated in prior Office actions, heteroplasmy, such as in the case of the generation of Dolly, may occur, but cross-species NT in a general sense remains unpredictable. Applicants argue that their own data, showing *B. taurus*/*B. gaurus* NT, a successful *B. javanicus*/*B. taurus* NT, and *Ovis/Ovis* NT present the predictability in the art of cross species NT. It is noted that the breadth of the claims is not limited to the sub-species NT, such as the cited examples. The breadth of the claims encompass the transfer of a bovine somatic cell into an enucleated ovine oocyte, for example. This has clearly been shown to be unpredictable for reasons of record. Applicants point to Chen to show evidence of the totipotency of cells produced by NT units. See p. 20 of Applicants' Response. Chen has been considered but not found to be persuasive. Firstly, Chen fails to show totipotency of the NT-produced cells because they fail to show that the NT units can develop beyond the blastocyst stage. Totipotency, as an art-recognized definition, is evidenced by the generation of an animal, which the instant specification fails to provide teachings or evidence for. Applicants argue that the cited art of Gardner in the prior Office action fails to disclose the state of the art for the instant invention and fail to provide relevant teachings with regard to the current specification. See pp. 20-21 of Applicants' response. It is noted that with regard to the instant application, the ES cells, as claimed are not enabling for reasons of record. Particularly, that the specification fails to show or provide teachings with regard to the pluripotency or totipotency of the cells. See prior Office action. Applicants argue that the cited work of Hammer is not relevant to the instant invention because Hammer describes IVF derived embryos and not production of NT units, as described in the instant invention. Applicants' arguments are not found to be persuasive. It is noted that Hammer states that the results found, such as the abnormalities of feto-maternal incompatibilities, and other placental abnormalities have been observed in cloned mammals as well. See p. 1452, 2nd paragraph of Hammer, and pp. 7-8 of the prior Office action.

Applicants' amendments to the claims have not been entered, thus the prior rejection of claims 51-83, 86 and 117 is maintained for reasons of record.